

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
**2035.015B**

In Re Application Of: **WISNIEWSKI**

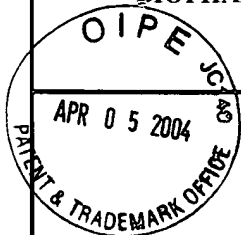
Serial No.  
**10/634,231**

Filing Date  
**August 5, 2003**

Examiner  
**Unassigned**

Group Art Unit  
**1723**

Title: **SYSTEMS AND METHODS FOR THAWING, MIXING AND PROCESSING**  
**BIOPHARMACEUTICAL MATERIALS**



Address to:  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
2035.015B

In Re Application: **WISNIEWSKI**

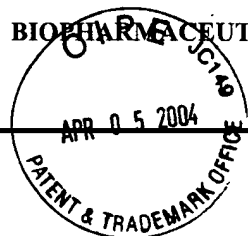
Serial No.  
10/634,231

Filing Date  
August 5, 2003

Examiner  
Unassigned

Group Art Unit  
1723

**SYSTEMS AND METHODS FOR THAWING, MIXING AND PROCESSING  
BIOPHARMACEUTICAL MATERIALS**



**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **08-1935**  
as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit  
account is being facsimile transmitted to the United States  
Patent and Trademark Office (F:

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Typed or Printed Name of Person Signing Certificate

**Certificate of Mailing by First Class Mail**

I certify that this document and fee is being deposited  
on **April 1, 2004** with the U.S. Postal Service  
as first class mail under 37 C.F.R. 1.8 and is  
addressed to the Commissioner for Patents, P.O. Box  
1450, Alexandria, VA 22313-1450.

\_\_\_\_\_  
Signature of Person Mailing Correspondence

Victor A. Cardona, Esq.

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Certificate

**\*This certificate may only be used if paying by  
deposit account.**

\_\_\_\_\_  
Signature

Dated: **April 1, 2004**

**VICTOR A. CARDONA, ESQ.**

Attorney for Applicant - Registration No. 44,589

**HESLIN ROTHENBERG FARLEY & MESITI P.C.**

5 Columbia Circle

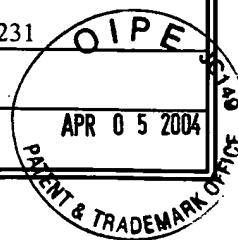
Albany, New York 12203

Telephone: 518-452-5600

Facsimile: 518-452-5579

CC:

INFORMATION DISCLOSURE CITATION	Docket No. 2035.015B	Serial No. 10/634,231
	Applicant: Wisniewski	
	Filing Date: August 5, 2003	Group: 1723



U.S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA	1,855,658	11/18/1929	Whipple <i>et al.</i>			
	AB	2,757,375	10/06/1953	Rieutord <i>et al.</i>	259	56	
	AC	3,389,974	06/25/1968	Barattini <i>et al.</i>	165	84	
	AD	3,830,474	08/20/1974	Tannenbaum	259	59	
	AE	4,178,776	12/18/1979	Baldus <i>et al.</i>	62	538	
	AF	4,336,435	06/22/1982	Kashyap <i>et al.</i>	219	10.55	
	AG	4,385,524	05/31/1983	Cappel	73	663	
	AH	4,473,739	09/25/1984	Scheiwe <i>et al.</i>	366	209	
	AI	4,652,712	03/24/1987	Zeipel	219	10.55	
	AJ	4,801,777	01/31/1989	Auerbach	219	10.55M	
	AK	4,843,827	07/04/1989	Peppers	62	73	
	AL	4,954,679	09/04/1990	Harms <i>et al.</i>	219	10.55	
	AM	5,243,833	09/14/1993	Coelho <i>et al.</i>	62	376	
	AN	5,520,885	05/28/1996	Coelho <i>et al.</i>	422	101	
	AO	5,524,706	06/11/1996	Nakamura <i>et al.</i>	165	47	
	AP	5,535,598	07/16/1996	Cothorn <i>et al.</i>	62	356	
	AQ	5,616,268	04/01/1997	Carr	219	687	
	AR	5,779,974	07/14/1998	Kuzyk	422	44	
	AS	5,863,715	01/26/1999	Rajotte <i>et al.</i>	435	1.3	
	AT	5,873,254	02/23/1999	Arav	62	63	
	AU	5,939,023	08/17/1999	Coelho <i>et al.</i>	422	101	
	AV	5,999,701	12/07/1999	Schmidt	392	470	

Examiner	Date Considered
----------	-----------------

INFORMATION DISCLOSURE CITATION	Docket No. 2035.015B	Serial No. 10/634,231
	Applicant: Wisniewski	
	Filing Date: August 5, 2003	Group: 1723

	AW	6,007,773	12/28/1999	Kuzyk	422	44	
	AX	6,196,296	03/06/2001	Wisniewski	165	47	
	AY	6,299,344	10/09/2001	Tannenbaum	366	212	
	AZ	6,384,380	05/07/2002	Faries, Jr. <i>et al.</i>	219	385	
	AAA	6,387,322	05/14/2002	Gallus	422	38	

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	Date	Country	Class	Subclas s	Translation	
							Yes	No
	BA	FR 2501057	10/09/1981	FRANCE	B01F 11/00.			X
	BB	DE 3047784	07/01/1982	GERMANY	C12N 5/00			X
	BC	JP 63-7829	01/13/1988	JAPAN	B01F011/00		Abstract	X
	BD	JP 63-296831	12/02/1988	JAPAN	B01F011/00		Abstract	X
	BE	JP 2-187138	07/23/1990	JAPAN	B01f011/00		Abstract	X
	BF	JP 2-261371	10/24/1990	JAPAN	C12M001/00		Abstract	X
	BG	JP 4-330271	11/18/1992	JAPAN	C12M001/02		Abstract	X
	BH	WO 97/24152	07/10/1997	PCT	A61M 5/44			X
	BI	WO 98/34078	08/06/1998	PCT	F25D 31/00		X	
	BJ	WO 00/72902	12/07/2000	PCT	A61M 5/44		X	

### Other Documents (including Author, Title, Date, pertinent public. etc.)

	CA	Quan <i>et al.</i> , "Effects of Vibration on Ice Contact Melting within Rectangular Enclosures," J. of Heat Transfer, Vol. 120, 1998, pp. 518-520
	CB	Wisniewski <i>et al.</i> , "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product", Proceedings of the International Congress: Advanced Technologies for Manufacturing of Aseptic & Terminally Sterilized Pharmaceutical & Biopharmaceuticals ; Base, Switzerland, February 17-19, 1992: pp. 132-140
	CC	Wisniewski <i>et al.</i> , "Large-Scale Freezing and Thawing of Biopharmaceutical Products", Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation; Drug Manufacturing Technology Series: Vol. 2 pp. 7-59

Examiner	Date Considered
----------	-----------------

<b>INFORMATION DISCLOSURE CITATION</b>	<b>Docket No.</b> 2035.015B	<b>Serial No.</b> 10/634,231
	<b>Applicant:</b> Wisniewski	
	<b>Filing Date:</b> August 5, 2003	<b>Group:</b> 1723

	CD	Wisniewski, R., "Developing Large -Scale Cryopreservation Systems for Biopharmaceutical Products", Bio-Pharm; June 1998: pp. 50-60
	CE	Wisniewski <i>et al.</i> , "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product", Pharm Tech Conference; 16-19 September 1996, Sheraton Meadowlands, East Rutherford, New Jersey; pp 385-92

Examiner	Date Considered
----------	-----------------